

respectfully traverse the restriction between Groups II and III and, therefore, respectfully request reconsideration and withdrawal of the restriction imposed between the claims of Groups II and III.

I. The Restriction Between the Claims of Groups II and III Is Traversed

A. The Restriction

According to the action:

Invention groups I-IV, are related as product and process of making a product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product [*sic*, process] as claimed could be used to make at least one materially different process [*sic*, product] as demonstrated throughout the specification and Invention group IV, which is directed to a different process/method for preparing same or different products.

See the action, at pp. 3 and 4 (citing MPEP § 806.05(f) (8th ed., Aug. 2001). Furthermore, according to the action:

In the instant case the different inventions are drawn to distinct processes of preparing same or different compound, requiring different search strategies because of the different reactive steps and conditions involved in each group and to search all the above groups in a single application would be an undue burden on the Examiner. Therefore a separate search considerations are involved, which would impose a burden if unrestricted. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

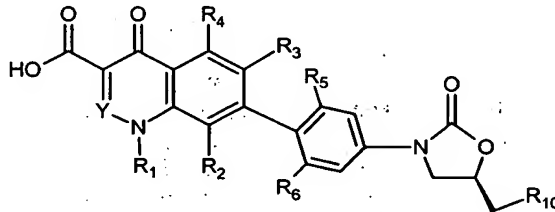
See the action, at p. 4. Based on the foregoing passages, it is unclear to the applicants on which position of MPEP § 806.05(f), the U.S. Patent and Trademark Office (PTO) relies for its restriction between the claims of Groups II and III. The PTO appears to take the position of subpart (1) of MPEP § 806.05(f), which states "that the process *as claimed* is not an obvious process for making the product and the process *as claimed* can be used to make other and different products," and/or the position of subpart (2) of MPEP § 806.05(f), which states "that the product *as claimed* can be made by another and materially different process" (emphases in original). On whichever of the two positions the PTO relies, the applicants respectfully traverse the restriction between the compound claims of Group II and the process claims of Group III.

B. The Standard for Requiring Restriction Has Not Been Met

It is respectfully submitted that the action does not provide an adequate basis for the restriction imposed between the claims of Group II and III.

As previously noted herein, for a restriction requirement between a compound and a process for its manufacture to be proper, MPEP § 806.05(f) requires "that the process as *claimed* is not an obvious process for making the product and the process as *claimed* can be used to make other and different products" and/or "that the product as *claimed* can be made by another and materially different process" (emphases in original). In other words, only if the claimed process is an unobvious process for making the compound *and* the claimed process can be used to make other and different compounds, would restriction be proper. Alternatively, or additionally, only if there are processes materially different from those claimed in the application (i.e., processes that would not have to be searched with the processes recited in the claims of Group III), would restriction be proper, since the rule is intended to avoid requiring the PTO to perform two searches in a single application.

According to the action, the processes that are materially different from the process recited in claims 22 and 23 are "demonstrated throughout the specification and Invention group IV." The process claims of Group IV are directed to the manufacture of:



by contacting a boronic acid with a specific quinolone in the presence of a palladium catalyst. In stark contrast, however, process claims 22 and 23 of Group III are directed to a process of making the boronic acid. Thus, the statement in the action relative to Group IV is correct to the extent the process recited in the claims of Group IV is different than the process recited in the claims of Group III. However, contrary to statements made in the action, the process recited in the claims of Group IV *cannot* be used to make the specific boronic acid sought to be made by the process recited in the claims of Group III. Indeed, that is ostensibly a basis on which restriction has been imposed between the claims of Groups III and IV.

The remainder of the action, which refers to processes "demonstrated throughout the specification," lacks necessary specificity on which a more meaningful response can be formulated. There are numerous processes disclosed in the specification to make various compounds. However, the action does not specify any one compound or groups of compounds (e.g., the compounds recited in the claims of Group II) that are made by more

than one process, much less a process materially different than the one recited in the claims of Group III.

The action neither expressly admits that the process recited in the claims of Group III is an unobvious process for making the compounds recited therein nor cites to any evidence that the process recited in the claims of Group III can be used to make other and different compounds. Both of the admission and citation are necessary to maintain the restriction if the PTO is relying on subpart (1) of MPEP § 806.05(f) as the basis for restriction. If neither the admission nor citation are provided, then necessary to the PTO's requirement for restriction is the position that the process claims 22 and 23 and the suggested method(s) be materially different processes and that the compounds recited in claims 20 and 21 can be made by all such processes. However, the action cites to no such evidence. Consequently, the restriction between the Groups II and III should be withdrawn.

**C. Admissions Concerning the Patentability of the Claims
Result if the PTO Maintains the Restriction Requirement
Between Groups II and III**

Should the PTO maintain the restriction between Groups II and III, then the PTO effectively admits that the process recited in claims 22 and 23 is patentable over processes "demonstrated throughout the specification" and those recited in the claims of Group IV (e.g., contacting a specific boronic acid with a specific quinolone in the presence of a palladium catalyst) or the PTO admits that the process recited in claims 22 and 23 is an unobvious process for making the compounds recited therein. Additionally, the PTO admits that claims 22 and 23 are patentable (i.e., distinct) over the disclosures of claims 20 and 21, and vice versa. These are the only logical admissions based on the statements in MPEP § 802.01 that the distinctness required for restriction means that the subjects, including "process and product made, ... ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" MPEP § 802.01 (8th ed., Aug. 2004) (emphases in original). Moreover, these PTO admissions are necessary to entry of the restriction requirement and may be relied upon by the applicants during examination of this and continuing applications, unless the restriction between the claims of Groups II and III is withdrawn.

Moreover, the restriction between Groups II and III should be withdrawn because the restriction presents potential double-patenting issues. For example, 35 USC § 121:

prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. ... This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a

heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

MPEP § 804.01 (8th ed., Aug. 2001) (emphasis added).

D. Search and Examination of All Claims in Groups II and III Can Be Made Without a Serious Burden on the PTO

The restriction requirement between Groups II and III is further traversed because there is no evidence — other than the assertions in the action — that search and examination of the Group II and III claims would be a serious burden on the PTO. Indeed, the action admits that the searches relative to Groups II and III would occur in the *same* class — class 548. See the action, at p. 2.

It is submitted that a complete search directed to the compounds recited in the claims of Group II would require a search directed to the process of making those compounds recited in the claims of Group III, and vice versa. As admitted by the PTO in the action, Groups II and III are directed to similar subject matter — Group II being drawn to intermediate compounds classified in class 548, and plethora of subclasses, and Group III being drawn to a process for preparing a compound classified in class 548, and plethora of subclasses. Since search and examination of all claims of Groups II and III can be made without a serious burden on the PTO, it would be wasteful of the time, effort, and resources of both the applicants and the PTO to prosecute claims directed to the intermediate compounds and a process of making the compounds in separate applications.

Additionally, if the restriction between the claims of Groups II and III is maintained, the applicants will likely incur substantial additional prosecution costs associated with filing one or more divisional applications, and the PTO will be required to perform duplicative searches. Thus, withdrawal of the restriction between the claims of Groups II and III will reduce the burden on the applicants *and* the PTO. In view of the foregoing, the applicants respectfully request that the requirement for restriction between the claims of Groups II and III be withdrawn.

II. Provisional Election

Pursuant to the requirements of 37 CFR § 1.143, the applicants hereby elect the compound claims of Group II in response to the restriction requirement and the compound of claim 21 in response to the election of species requirement. Claims readable on this election include claims 20 and 21.